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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,220	01/17/2002	David O'Hagan	11101-008	2186

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EXAMINER

SNAY, JEFFREY R

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,220

Applicant(s)

O'HAGAN, DAVID

Examiner

Jeffrey R. Snay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 04/22/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-8 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Walt et al ('540).

Walt et al disclose an analytical method which comprises all of the presently recited elements. Specifically, Walt et al teach an optical method for determining multiple analytes which comprises contacting a sample with a plurality of specifically reactive microspheres. Each microsphere includes a ligand which reacts with a fluorescent labelled analyte, such that specific binding of the analyte to a microsphere produces a detectable change in the optical emission of the microsphere. See e.g. column 3, lines 31-43. Furthermore, each bead is provided with an encoded signature, such that the particular bead, and thus the particular ligand carried by the bead, can be identified through decoding the signature (column 3, lines 43-54). The beads are so encoded by incorporation of dyes, and the dyes can be chromophores (column 3, lines 54-55). The disclosed method involves contacting a sample with the reactive microspheres, detecting an optical emission resulting from binding of a fluorescent

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labelled analyte, and decoding the dye combination of the responsive microsphere to identify the chemical functionality of that microsphere (see e.g. claim 1). The decoding of the chromophore signature dyes is accomplished by known techniques of absorption spectrometry. Chemical functionalities are determined from the decoded signal by comparison with a lookup table (e.g. column 14, lines 50-55).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler et al ('180) in view of Walt et al ('540) and Van den Engh et al ('469).

Chandler discloses a method for detecting analytes in a sample which comprises contacting the sample with beads and optically analyzing each bead through flow cytometry. Each bead comprises an fluorescent label for identification of the bead and consequently the chemical functionality associated with the bead. Optically detectable specific binding partners are also provided on each bead. In operation, the beads are combined with the sample fluid to permit specific binding between the analyte and the chemical functionality on the bead. The beads are then run through the flow cytometer and each bead is categorized according to the optical identifier. Simultaneously, optical emission is analyzed to detect the presence of a bound analyte. The two optical signals are construed to determine the analyte in the sample. See particularly column 6, lines 9-27, of Chandler et al. Finally, Chandler teaches that the analyzed beads are separated and collected with a cell sorter (column 5, lines 34-37).

The method of Chandler et al differs from the claimed invention in that it utilizes fluorescent identifiers for encoding the beads, rather than color-based identifiers, and further in that it fails to provide details of the cell sorter.

Walt et al, described fully above, teaches a similar analytical method in which microspheres having a specifically reactive chemical functionality are further provided with an optical coding. Walt et al teach that both fluorescent identifiers and chromophore identifiers can be used to provide addressable beads. Thus, it would have been obvious to one of ordinary skill in the art to substitute color-based coding of the beads for the fluorescent labels in the method of Chandler et al as an art recognized equivalent for accomplishing the desired capability of bead identification and classification.

Van den Engh et al disclose a flow cytometer in operational association with a cell sorter. The disclosed cell sorter includes parallel walls which can be selectively energized in order to deflect a particularly identified bead into a desired collector. See Figure 1. It would have been obvious to one of ordinary skill in the art to provide the cell sorting techniques of Van den Engh et al in the method of Chandler et al in order to accomplish the desired result of sorting the analyzed beads passing through the flow cytometer. It is noted that the presently recited alternative means for deflecting individual particles, such as by jets of air or magnetic forces, were well known in the field of flow cytometry sorters and would have constituted art recognized alternatives to the electrostatic deflector of Van den Engh et al.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as general background information related to applicant's field of endeavor.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (571) 272-1264. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey R. Snay
Primary Examiner
Art Unit 1743

jrs